

## REMARKS

Support for claims 28-32 can be found throughout the specification, e.g., Page 6, lines 24-28.

### 3. Specification Objections

The specification has been amended on Pages 6 and 31 as suggested.

### 4., 5. Claims Objections

The claims have been clarified to address the objections.

6., 7. As stated in the specification, the claimed polynucleotide is over-expressed in breast cancer tissues. See, e.g., Specification, beginning on Page 2, lines 20-23. Thus, polynucleotides of SEQ ID NO 1 would be useful as diagnostic markers for breast cancer. This utility is adequate to meet the requirements of 35 U.S.C. §101. See, e.g., *Utility Guidelines*, Pages 69-70, where a marker for cancer is described as having a well-established utility. These pages are attached for the examiner's convenience (Exhibit 1).

It is stated on, e.g., Page 4, lines 14-16 of the Office action, that the specification "does not enlighten the artisan as to why this conclusions was reached, does not enlighten the artisan as to the methods used to make the determination." According to the M.P.E.P. 2107.02:

In most cases, an applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. 101. See, e.g., *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *In re Irons*, 340 F.2d 974, 144 USPQ 351 (CCPA 1965); *In re Langer*, 503 F.2d 1380, 183 USPQ 288 (CCPA 1974); *In re Sichert*, 566 F.2d 1154, 1159, 196 USPQ 209, 212-13 (CCPA 1977). As the Court of Customs and Patent Appeals stated in *In re Langer*:

As a matter of Patent Office practice, a specification which contains a disclosure of utility which corresponds in scope to the subject matter sought to be patented must be taken as sufficient to satisfy the utility requirement of §101 for the

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entire claimed subject matter unless there is a reason for one skilled in the art to question the objective truth of the statement of utility or its scope.

...

Thus, Langer and subsequent cases direct the Office to presume that a statement of utility made by an applicant is true. See *In re Langer*, 503 F.2d at 1391, 183 USPQ at 297; *In re Malachowski*, 530 F.2d 1402, 1404, 189 USPQ 432, 435 (CCPA 1976); *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995). For obvious reasons of efficiency and in deference to an applicant's understanding of his or her invention, when a statement of utility is evaluated, Office personnel should not begin by questioning the truth of the statement of utility. Instead, any inquiry must start by asking if there is any reason to question the truth of the statement of utility. This can be done by simply evaluating the logic of the statements made, taking into consideration any evidence cited by the applicant. If the asserted utility is credible (i.e., believable based on the record or the nature of the invention), a rejection based on "lack of utility" is not appropriate.

The examiner has given no reasonable basis for doubting the utility of the claimed invention.

Although unnecessary, attached is a declaration by Dr. Zairen Sun under §1.132 which provides additional evidence using RT-PCR technology that the claimed polynucleotides are up-regulated in breast cancer tissues. See, e.g., Paragraph No. 5 of Dr. Sun's declaration.

8., 9. Claims 3 and 4 have been amended to recite that the polynucleotide is "human." As indicated on Page 5, lines 9-12, of the specification, the term "human" indicates that the polynucleotide is naturally-occurring and obtained from natural sources. The specification provides ample guidance for selecting other human alleles of the SEQ ID NO 1 from naturally-occurring sources. These claims also clearly state that the polynucleotide codes for a human Urb-ctf. To the extent this was not already clear, the claim has been amended to clarify that it codes for a "full-length" human Urb-ctf. The Patent Office has not provided any factual evidence to support the allegation that it would require undue experimentation to practice the full breadth of the claims.

The discussion of "complement" on Pages 18-19 of the Office action is not understood. It is

the undersigned's understanding that it is acceptable to claim a sequence (e.g., SEQ ID NO 1) and then to claim the complement to it. The normal meaning of the term covers 100% complementarity. There are a legion of patents which use the term in this precise way. It is not clear why the examiner is choosing a completely perverted interpretation of the term, i.e., where the term "complement" is used to broaden the claim to cover complements of it that are far broader than the recited sequence.

11. Applicants have disclosed a full-length open reading frame for a human Urb-ctf. In addition to coding sequence, this polynucleotide also comprises 5' and 3' sequences. See, e.g., SEQ ID NO 1. Example 8 of the Written Description Guidelines states clearly that such disclosure complies with the written description requirement. See, Exhibit 2, Pages 34-35. Similarly, applicant should be able to claim fragments of it. See, e.g., Claim 5. The rejection should be withdrawn.

12. Rejection under 35 U.S.C. §102(b) as being anticipated by Boehringer Mannheim Biochemicals Catalog. This rejection is respectfully traversed.

Claim 1 has been clarified to recite that the polynucleotide sequence codes without interruption for "amino acids 1-614 as set forth in SEQ ID NO 2, or a complement thereto." This amendment was absolutely unnecessary since the claimed subject matter was already clear. This sequence is not disclosed in the cited Catalog pages, and therefore it is incumbent upon the examiner to withdraw the rejection.

Claim 5 recites an "isolated polynucleotide ... which is specific for human Urb-ctf..." The primer described in the Boehringer Mannheim Biochemicals Catalog is a "mixture of hexanucleotides containing all possible 6-nucleotide combinations." This mixture is not "specific" for Urb-ctf, but would – using the examiner's logic – hybridize to every single gene in every single organism (including viruses) on earth. The term "specific" is defined in the specification, e.g., Page 13, lines 1-9.

Claim 6 recites specific sequences, e.g., "amino acids 1-263" or "459-614" of SEQ ID NO 2.

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These specific sequences are clearly not disclosed on Page 93 of the Boehringer Mannheim Biochemicals Catalog.

Claim 12 was rejected, but on the Office Action Summary, it is indicated as being withdrawn from consideration. Therefore, unless advised otherwise, applicant assumes its inclusion in the rejection was inadvertent.

13. Rejection under 35 U.S.C. §102(b) as being anticipated by Carninci et al. or Shibata et al. This rejection is respectfully traversed.

Neither of the cited references discloses a polynucleotide sequence which codes without interruption for human Urb-ctf comprising amino acids 1-614 as set forth in SEQ ID NO 2, or a complement thereto. See, Claim 1. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Thus, the rejection of Claim 1 should be withdrawn.

It is stated in the Office action "that any polynucleotide that codes for any of these specific amino acids in any position of the polypeptide is specific for human Urb-ctf." This is a perverted reading of the claim. The claim clearly recites that the polynucleotide sequence is "selected from SEQ ID NO 1." Therefore, the position of the claimed amino acid is not arbitrary, but is determined by the sequence of SEQ ID NO 1. To clarify this, the claim has been amended to recite that "the polynucleotide comprising the position which corresponds to amino acid 38 of SEQ ID NO 2," etc. This amendment does not change the claim scope in any way, since it merely clarifies what the skilled worker, in light of the specification, would have already understood to be claimed.

14. Rejection under 35 U.S.C. §102(b) as being anticipated by Konno et al. This rejection is respectfully traversed.

Konno et al. do not disclose or suggest, e.g., a polynucleotide comprising a polynucleotide

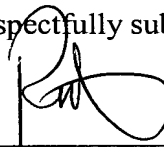
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sequence selected from SEQ ID NO 1 and which comprises the position which corresponds to amino acid 38, 68, 76-77, 119, 143-144, 161, 583, or 606 of SEQ ID NO 2, or complements thereof. Consequently, the cited reference can not anticipate the claims, and the rejection should be withdrawn.

In view of the above remarks, favorable reconsideration is courteously requested. If there are any remaining issues which could be expedited by a telephone conference, the Examiner is courteously invited to telephone counsel at the number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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